

ATTORNEY-CLIENT PRIVILEGED COMMUNICATION  
DRAFT for Discussion Purposes

Bates et al.  
10/618,977

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

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**Listing of Claims:**

Please cancel claims 1-9.

10. (Currently amended). A coated medical device comprising:  
an inflatable balloon having a base material layer, and a balloon bioactive material layer posited on said base material layer.
11. (Currently amended). The coated material medical device according to claim 10, further comprising an implantable stent including a stent base material layer and a stent bioactive material layer posited thereon on the stent base material layer, wherein said stent is disposed around said balloon.
12. (Currently amended). The coated medical device according to claim 10, wherein the balloon bioactive material layer posited on the stent and the balloon base material comprises a is lipophilic bioactive material layer.
13. (Currently amended). The coated medical device according to claim 10, wherein the balloon bioactive material layer on said balloon comprises a is lipophilic material layer and extends beyond the ends of the stent disposed around said balloon.
14. (Currently amended). The medical device according to claim 11, wherein the layer of base material of the structure stent base material layer comprises at least one of: stainless steel, tantalum, titanium, nitinol, gold, platinum, inconel, iridium, silver, tungsten, or another biocompatible metal, or alloys of any of these;

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10/618,977

carbon or carbon fiber; cellulose acetate, cellulose nitrate, silicone, polyethylene terephthalate, polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another biodegradable polymer, or mixtures or copolymers of these; a protein, an extracellular matrix component, collagen, fibrin or another biologic agent; or a suitable mixture of any of these.

Please cancel claim 15.

16. (Currently amended). The medical device according to claim 10, wherein the base material layer comprises at least one of: stainless steel, tantalum, titanium, nitinol, gold, platinum, inconel, iridium, silver, tungsten, or another biocompatible metal, or alloys of any of these; carbon or carbon fiber; cellulose acetate, cellulose nitrate, silicone, irradiated polyethylene, polyethylene terephthalate, polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another biodegradable polymer, PEBAX, nylon or mixtures or copolymers of these; a protein, an extracellular matrix component, collagen, fibrin or another biologic agent; or a suitable mixture of any of these.

Please cancel claims 17-18.

19. (Currently amended). The coated medical device according to claim 10, wherein the balloon bioactive material layer comprises at least one of: paclitaxel, a taxane or other paclitaxel analogue; estrogen or estrogen derivatives; heparin

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10/618,977

or another thrombin inhibitor, hirudin, hirulog, argatroban, D-phenylalanyl-L-poly-L-arginyl chloromethyl ketone, or another antithrombogenic agent, or mixtures thereof; urokinase, streptokinase, a tissue plasminogen activator, or another thrombolytic agent, or mixtures thereof; a fibrinolytic agent; a vasospasm inhibitor; a calcium channel blocker, a nitrate, nitric oxide, a nitric oxide promoter or another vasodilator; an antimicrobial agent or antibiotic; aspirin, ticlopidine or another antiplatelet agent; vascular endothelial growth factor (VEGF) or analogues thereof; colchicine or another antimitotic, or another microtubule inhibitor; cytochalasin or another actin inhibitor; a remodeling inhibitor; deoxyribonucleic acid, an antisense nucleotide or another agent for molecular genetic intervention; a cell cycle inhibitor (such as the protein product of the retinoblastoma tumor suppressor gene, or analogues thereof); GP IIb/IIIa, GP Ib-IX or another inhibitor or surface glycoprotein receptor; methotrexate or another antimetabolite or antiproliferative agent; an anti-cancer chemotherapeutic agent; dexamethasone, dexamethasone sodium phosphate, dexamethasone acetate or another dexamethasone derivative, or another anti-inflammatory steroid; prostaglandin, prostacyclin or analogues thereof; an immunosuppressive agent (such as cyclosporine or rapamycin); an antibiotic (such as streptomycin), erythromycin or vancomycin; dopamine, bromocriptine mesylate, pergolide mesylate or another dopamine agonist; <sup>60</sup>Co, <sup>192</sup>Ir, <sup>32</sup>P, <sup>111</sup>In, <sup>90</sup>Y, <sup>99m</sup>Tc or another radiotherapeutic agent; iodine-containing compounds, barium-containing compounds, gold, tantalum, platinum, tungsten or another heavy metal functioning as a radiopaque agent; a peptide, a protein, an enzyme, an extracellular matrix component, a cellular component or another biologic agent; captopril, enalapril or another angiotensin converting enzyme (ACE) inhibitor; ascorbic acid, alphatocopherol, superoxide dismutase, deferoxamine, a 21-aminosteroid (lasaroid) or another free radical scavenger, iron chelator or antioxidant; angiopeptin; a <sup>14</sup>C-, <sup>3</sup>H-, <sup>131</sup>I-, <sup>32</sup>P- or <sup>36</sup>S-radiolabelled form or other radiolabeled form of any of the foregoing; or a mixture of any of these.

Please cancel claim 20.

ATTORNEY-CLIENT PRIVILEGED COMMUNICATION  
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10/6/18, 977

Please enter the following new claims:

21. (New). The coated medical device of claim 10, further comprising a layer comprising a hydrophilic material posited between the base material and the bioactive material.

22. (New). The coated medical device of claim 21, where the layer comprising the hydrophilic material is a slip coating layer.

23. (New). The coated medical device of claim 10, where the balloon bioactive material is lipophilic and comprises paclitaxel, and where the coated medical device further comprises a hydrophilic material posited between the base material and the balloon bioactive material.

24. (New). A coated medical device comprising:

an inflatable balloon having an expandable outer surface,  
a hydrophilic material posited on the expandable outer surface; and  
a lipophilic balloon bioactive material posited on the expandable outer surface.

25. (New). The coated medical device of claim 24, where the lipophilic balloon bioactive material comprises a bioactive selected from the group consisting of: an immunosuppressive agent and a compound that inhibits arterial smooth muscle cell proliferation.

26. (New). The coated medical device of claim 24, where the balloon bioactive material comprises paclitaxel.

27. (New). A method of manufacturing a coated medical device comprising:

ATTORNEY-CLIENT PRIVILEGED COMMUNICATION  
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Bates et al.  
10/618,977

providing an inflatable balloon having inflated and deflated configurations;

inflating the inflatable balloon, the inflatable balloon comprising a balloon base material;

depositing a hydrophilic layer on the balloon base material; and  
depositing a bioactive material on the hydrophilic layer.

28. (New). The method of claim 27, where the bioactive material is lipophilic.
29. (New). The method of claim 27, where the hydrophilic layer is deposited on the balloon base material while the inflatable balloon is in the inflated configuration.
30. (New). The method of claim 27, where the bioactive material is deposited while the inflatable balloon is in the inflated configuration.
31. (New). The method of claim 27, where the balloon base material comprises at least one of irradiated polyethylene, polyethylene terephthalate, polyurethane, polyamide, polyester, polyorthoester, polyanhydride, polyether sulfone, polycarbonate, polypropylene, high molecular weight polyethylene, polytetrafluoroethylene, or another biocompatible polymeric material, or mixtures or copolymers of these; polylactic acid, polyglycolic acid or copolymers thereof, a polyanhydride, polycaprolactone, polyhydroxybutyrate valerate or another biodegradable polymer, PEBAK, nylon or mixtures or copolymers of these.